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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,376	03/09/2001	Gary Van Nest	377882001700	8397

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,376

Applicant(s)

NEST ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005 and 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,12-55,58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11,56,57 and 60-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-23-04 and 11-2-04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communications filed 1-19-05 and 9-23-04.

Claims 1-66 are pending in the instant application.

Election/Restrictions

Claims 3, 4, 12-55, 58 and 59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1-19-05.

Applicant's election without traverse of Group III, claims 1, 2, 5-11, 56, 57 and 60-66 in the reply filed on 1-19-05 is acknowledged.

Response to Arguments and Amendments

Applicant's arguments filed 9-23-04, with respect to the rejection(s) of claim(s) 1-11 and 56-66 under 35 U.S.C. 102(b) and 112, first paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as set forth below.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-11, 56, 57, 60-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al.

Schwartz et al (WO 98/55495) teach pharmaceutical compositions (and kits) comprising an immunomodulatory polynucleotide which comprises the ISS sequence of SEQ ID NO: 1 (which comprises the sequence 5'-T-C-G-3', and which comprises the motif 5'-puring, purine, C,G,pyrimidine, pyrimidine, C,G-3'), and which polynucleotide is covalently attached to a non-biodegradable, solid microcarrier between 10nm and 10um in size, and which ISS-microcarrier complex is optionally antigen-free (see accompanying sequence alignment data between SEQ ID NO: 1 of the instant application and Acc. No. AAV80097 of WO 98/55495; see *a/so* the abstract on p. 1, pa. 12, lines 9-28; p. 14, lines 15-30; p. 15, lines 5-18; p. 15, line 40-p. 16, line 3; p. 16, lines 18-29; p. 24, lines 3-6; claim 43).

Claims 1, 2, 5-11, 56, 57, 60-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Raz et al.

Raz et al (USPN 6,589,940) teach pharmaceutical compositions (and kits) comprising an immunomodulatory polynucleotide which comprises the ISS sequence of SEQ ID NO: 1 (which comprises the sequence 5'-T-C-G-3', and which comprises the motif 5'-purine, purine, C,G,pyrimidine, pyrimidine, C,G-3'), and which polynucleotide is covalently attached to a non-biodegradable, solid microcarrier between 10nm and 10um in size, and which ISS-microcarrier complex is optionally antigen-free (see accompanying sequence alignment data between SEQ ID NO: 1 of the instant application and SEQ ID NO: 2 from USPN 6,589,940; see *also* the abstract, col. 14, lines 50-67; col. 15, lines 31-41; col. 17, lines 10-28; col. 20, line 61-col. 21, line 46; col. 27, lines 19-36).

Claims 1, 2, 5-9, 56, 57, 60-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al.

Schwartz et al (USPN 6562,798) teach pharmaceutical compositions (and kits) comprising an immunomodulatory polynucleotide which comprises an ISS sequence (which comprises the sequence 5'-T-C-G-3'), and which polynucleotide is covalently attached to a non-biodegradable, solid microcarrier between 10nm and 10um in size, and which ISS-microcarrier complex is optionally antigen-free (see abstract; col. 12, lines 41-61; col. 13, line 60-col. 14, line 12; table 1 in col. 25).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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